

involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§ 11.121 [Reserved]

§ 11.122 Use of Federal funds.

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§ 11.123 Early termination of research support: Evaluation of applications and proposals.

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or

not the research was subject to Federal regulation).

§ 11.124 Conditions.

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

PART 17—INTERGOVERNMENTAL REVIEW OF DEPARTMENT OF TRANSPORTATION PROGRAMS AND ACTIVITIES

Sec.

- 17.1 What is the purpose of these regulations?
- 17.2 What definitions apply to these regulations?
- 17.3 What programs and activities of the Department are subject to these regulations?
- 17.4 [Reserved]
- 17.5 What is the Secretary's obligation with respect to Federal interagency coordination?
- 17.6 What procedures apply to the selection of programs and activities under these regulations?
- 17.7 How does the Secretary communicate with state and local officials concerning the Department's programs and activities?
- 17.8 How does the secretary provide states an opportunity to comment on proposed Federal financial assistance and direct Federal development?
- 17.9 How does the Secretary receive and respond to comments?
- 17.10 How does the Secretary make efforts to accommodate intergovernmental concerns?
- 17.11 What are the Secretary's obligations in interstate situations?
- 17.12 How may a state simplify, consolidate, or substitute federally required state plans?
- 17.13 May the Secretary waive any provision of these regulations?

AUTHORITY: Executive Order 12372, July 14, 1982 (47 FR 30959), as amended April 8, 1983 (48 FR 15887); sec. 401 of the Intergovernmental Cooperation Act of 1968, as amended (31 U.S.C. 6506); sec. 204 of the Demonstration Cities and Metropolitan Development Act of 1966, as amended (42 U.S.C. 3334).

SOURCE: 48 FR 29272, June 24, 1983, unless otherwise noted